



Provider Communication

Subject: FDA Authorizes Emergency Use of Intravenous Antiviral Peramivir for 2009 H1N1 Influenza for Certain Patients, Settings	Priority: High
Date: October 26, 2009	Message ID: ACSBNR10262009_1

Dear Hospital Providers,

The U.S. Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) for intravenous antiviral Peramivir for 2009 H1N1 Influenza for certain patients. Georgia Medicaid will accept EUA for the investigational antiviral drug peramivir intravenous (IV) in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection who are admitted to a hospital. Peramivir is the only intravenously administered influenza treatment currently authorized for use under EUA for 2009 H1N1 infections. The FDA press release is set forth below:

The U.S. Food and Drug Administration announced today that, in response to a request from the U.S. Centers for Disease Control and Prevention, it has issued an emergency use authorization (EUA) for the investigational antiviral drug peramivir intravenous (IV) in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection who are admitted to a hospital.

Specifically, IV peramivir is authorized only for hospitalized adult and pediatric patients for whom therapy with an IV drug is clinically appropriate, based on one or more of the following reasons:

1. the patient is not responding to either oral or inhaled antiviral therapy, or
2. when drug delivery by a route other than an intravenous route -- e.g., enteral (absorbed by the intestines) or inhaled -- is not expected to be dependable or feasible;
3. for adults only, when the clinician judges IV therapy is appropriate due to other circumstances.

The FDA has reviewed the available scientific data and has concluded that the criteria for authorizing the emergency use of IV peramivir have been met.

There are no FDA-approved intravenously administered antivirals for the treatment of influenza. Peramivir is the only intravenously administered influenza treatment currently authorized for use under EUA for 2009 H1N1 infections.

The EUA authority allows the FDA, based on the evaluation of available data, to authorize the use of unapproved or uncleared medical products or unapproved or uncleared uses of approved or cleared medical products following a determination and declaration of emergency, provided certain criteria are met. The authorization will end when the declaration of emergency is terminated or the authorization is revoked by the agency.

For more information, see <http://www.cdc.gov/h1n1flu/eua/> or call 1-800-CDC-INFO (1-800-232-4636).

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